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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	125889.101
First Inventor	Fetterman
Title	Method and System for...
Express Mail Label No.	EL968313899US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original and a duplicate for fee processing)
2. Applicant claims small entity status.
See 37 CFR 1.27.
3. Specification [Total Pages 47]
(preferred arrangement set forth below)
 - Descriptive title of the invention
 - Cross Reference to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference to sequence listing, a table, or a computer program listing appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings *(if filed)*
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
4. Drawing(s) (35 U.S.C. 113) [Total Sheets 10]
5. Oath or Declaration [Total Sheets 3]
 - a. Newly executed (original or copy)
 - b. Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 18 completed)
 - i. **DELETION OF INVENTOR(S)**
Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. Application Data Sheet. See 37 CFR 1.76

ADDRESS TO:
Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

7. CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)
8. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
 - a. Computer Readable Form (CRF)
 - b. **Specification Sequence Listing on:**
 - i. CD-ROM or CD-R (2 copies); or
 - ii. Paper
 - c. Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. Assignment Papers (cover sheet & document(s))
10. 37 CFR 3.73(b) Statement Power of *(when there is an assignee)* Attorney
11. English Translation Document *(if applicable)*
12. Information Disclosure Statement (IDS)/PTO-1449 Copies of IDS Citations
13. Preliminary Amendment
14. Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
15. Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
16. Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. Other: **Certificate of Mailing**.....

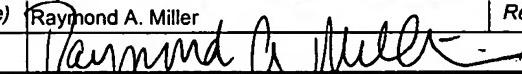
18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:

 Continuation Divisional Continuation-in-part (CIP) of prior application No.:

Prior application information: Examiner _____ Art Unit: _____
 For CONTINUATION OF DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference.
 The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS
 Customer Number: 21269 OR Correspondence address below

Name			
Address			
City	State	Zip Code	
Country	Telephone	Fax	

Name (Print/Type)	Raymond A. Miller	Registration No. (Attorney/Agent)	42,891
Signature			
	Date	November 25, 2003	

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

22581 U.S. PTO
10/722262

112503

15992
112503
U.S. PTO

PTO/SB/17 (10-03)

Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

 Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 930.00)

Complete if Known

Application Number	not yet assigned
Filing Date	November 25, 2003
First Named Inventor	Fetterman
Examiner Name	not yet assigned
Art Unit	not yet assigned
Attorney Docket No.	125889.101

METHOD OF PAYMENT (check all that apply)

 Check Credit card Money Order Other None Deposit Account:

Deposit Account Number	50-0436
Deposit Account Name	Pepper Hamilton LLP

The Director is authorized to: (check all that apply)

- Charge fee(s) indicated below Credit any overpayments
 Charge any additional fee(s) or any underpayment of fee(s)
 Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code (\$)	Fee Code (\$)		
1001 770	2001 385	Utility filing fee	385.00
1002 340	2002 170	Design filing fee	
1003 530	2003 265	Plant filing fee	
1004 770	2004 385	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	
SUBTOTAL (1)			(\$ 385.00)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
57	-20** = 19	x 9	= 333
Independent Claims	7	- 3** = 4	x 43 = 172
Multiple Dependent			= 0

Large Entity	Small Entity	Fee Description
Fee Code (\$)	Fee Code (\$)	
1202 18	2202 9	Claims in excess of 20
1201 86	2201 43	Independent claims in excess of 3
1203 290	2203 145	Multiple dependent claim, if not paid
1204 86	2204 43	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent
SUBTOTAL (2)		(\$ 505)

**or number previously paid, if greater; For Reissues, see above

3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for ex parte reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 420	2252 210	Extension for reply within second month	
1253 950	2253 475	Extension for reply within third month	
1254 1,480	2254 740	Extension for reply within fourth month	
1255 2,010	2255 1,005	Extension for reply within fifth month	
1401 330	2401 165	Notice of Appeal	
1402 330	2402 165	Filing a brief in support of an appeal	
1403 290	2403 145	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,330	2453 665	Petition to revive - unintentional	
1501 1,330	2501 665	Utility issue fee (or reissue)	
1502 480	2502 240	Design issue fee	
1503 640	2503 320	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 770	2809 385	Filing a submission after final rejection (37 CFR 1.129(a))	40.00
1810 770	2810 385	For each additional invention to be examined (37 CFR 1.129(b))	
1801 770	2801 385	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ 40.00)

(Complete if applicable)

Name (Print/Type)	Raymond A. Miller	Registration No. (Attorney/Agent)	42,891	Telephone	412.454.5000
Signature					
Date	November 25, 2003				

WARNING: Information in this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

APPLICANT: FETTERMAN, ET AL.

TITLE: A METHOD OF ASSESSING AND MANAGING RISKS
ASSOCIATED WITH A PHARMACEUTICAL PRODUCT

SERIAL NO.: Not yet assigned

ATTORNEY REF: 125889.0101

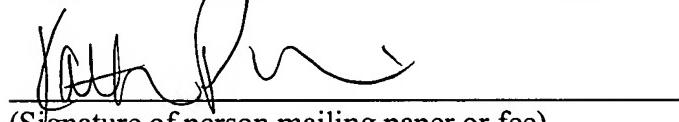
DATE OF DEPOSIT: November 25, 2003

EXPRESS MAIL NO. EL968313899US

I HEREBY CERTIFY THAT THIS PATENT APPLICATION IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE VIA UNITED STATES POST OFFICE EXPRESS MAIL UNDER 37 C.F.R. § 1.10 ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE COMMISSIONER OF PATENTS, MAIL STOP PATENT APPLICATION, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Kathleen Pujol

(Typed or printed name of person mailing paper or fee)



(Signature of person mailing paper or fee)

Documents Sent:

- | | |
|--|--|
| <input checked="" type="checkbox"/> Application (47 sheets) | <input checked="" type="checkbox"/> New Utility Application Transmittal |
| <input checked="" type="checkbox"/> Formal Drawings (10 sheets) | <input checked="" type="checkbox"/> Other Fee Transmittal & Check for \$930.00 |
| <input checked="" type="checkbox"/> Declaration | <input checked="" type="checkbox"/> Applicant Data Sheet |
| <input checked="" type="checkbox"/> Other Certificate of Mailing | <input checked="" type="checkbox"/> Assignment of Patent Application & Cover sheet |